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Oxydemeton-Methyl

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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EPA

Pesticide Fact Sheet

Name of Chemical: Oxydemeton-Methyl
Reason for Issuance: Registration Standard/Initiation of Special Review
Date Issued: 10/87
Fact Sheet Number: 144

1. Description of Chemical

Chemical name: S-[2-(Ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate

Common name: Oxydemeton-methyl

Other Chemical Names: Demeton-o-methyl; s-2-ethylsulphinylethyl-o,o-dimethyl phosphorothioate; metilmerkapto-fosoksiol; o,o-dimethyl-s-[2-(ethylsulfinyl) ethyl]phosphorothioate; demeston-s-methyl-sulfoxid;

Trade Names: R2170; Metasystemox; Metasystox-R; and Bay 21097

OPP Shaughnessy No.: 058702
Chemical Abstracts Service (CAS) No.: 301-12-2
Year of Initial Registration: 1961
Pesticide Type: Insecticide, Acaricide.
Chemical Family: Organophosphate
U.S. and Foreign Producers: Mobay Chemical Corp., U.S.A.; Bayer AG, West Germany.

2. Use Patterns and Formulations

Application sites: terrestrial food crops (vegetable, field tree fruit, and nut crops), terrestrial nonfood crops (ornamentals and forest trees), greenhouse nonfood crops (research crops not for consumption), domestic indoor and outdoor, and forestry (trunk injection only).

Types of Formulation: Oxydemeton-methyl is formulated in combination with trichlorfon, methoxychlor, carbaryl, dinocap, dicofol, or folpet. Single ai formulations consist of 0.48 to 4.0 lb/gal EC, 2%, 2.45%, and 13.5% EC and 50% P/T.

Types/Methods of Application: applied by broadcast spray using ground equipment or aircraft, soil injection, tree trunk injection.

3. Science Findings

Summary Science Statement:

Oxydemeton-methyl is an organophosphate compound. It is classified as Toxicity Category I due to its dermal toxicity, Toxicity Category II due to its inhalation and oral toxicity. Toxicity Category IV based on primary dermal irritation potential, and Toxicity Category III because of its ability to cause primary eye irritation. A 1-year dog feeding study conducted with the 50% concentrate of the technical material, instead of the technical grade, at dietary concentrations of 0, 0.0125, 0.125 and 1.25 mg/kg/day, showed inhibition of RBC and brain cholinesterase at the mid-dose. A new study with the technical grade is required. Submitted oncogenicity data are inadequate to allow an assessment of the oncogenic potential of oxydemeton-methyl. Based on available data, the Agency has determined that oxydemeton-methyl has the potential to induce reproductive effects in humans, and that that effect is of concern because of the potential exposure to applicators, mixers, and loaders who use products containing oxydemeton-methyl, and to field workers who may enter treated fields. Additional data are required to fully assess this concern. Additional toxicology and residue chemistry data are required for a reassessment of the tolerances of oxydemeton-methyl and its cholinesterase-inhibiting metabolites. Avian acute oral studies indicate toxicity ranges from moderately toxic (mallards) to highly toxic (rock dove). Eight-day dietary studies also show a wide range of toxicity from practically non-toxic (mallards) to highly toxic (bobwhite quail). Available data indicate oxydemeton-methyl is very highly toxic to daphnids, moderately toxic to isopods, highly toxic to amphipods, moderately to highly toxic to coldwater fish, slightly to moderately toxic to warmwater fish, and moderately toxic to estuarine crustaceans. Additional data are required for the Agency to complete its assessment of potential risks to avian and aquatic species.

Chemical Characteristics:

Physical/chemical properties of pure oxydemeton-methyl, and of the 53.1% FI[a] and 90% unregistered T:

Color: Colorless (P), yellow-brown (T), Yellow to amber (FI)
Physical state: liquid (P, FI)
Odor: Odorless (P), Typical sulfur-containing (T)
Melting Point: <10° C (P), <10° C (T)
Boiling Point: 106° C at 0.013 mbar (P)
Specific Gravity: 1.289 at 20° C (P), 1.03 at 20° C (FI)
Solubility: 10-100 g/100 ml of xylene, cyclohexanone, 2-propanol, and methylene chloride at 20° C (P). Miscible in water at 20° C (P).

[a] FI = 53.1% Formulation Intermediate; T = unregistered 90% Technical; P = Pure Active Ingredient;

Vapor Pressure: 3.8×10^{-5} mbar at 20° C (P)
Dissociation Constant: N/A
Octanol/Water Partition Coefficient: 0.18 (P)
pH: N/A

Toxicology Characteristics

Acute oral: Toxicity Category II
- Supplementary data indicates 50-80 mg/kg in the rat

Acute dermal: Toxicity Category I
- 112 and 152 mg/kg in female and male rats, respectively

Acute inhalation: Toxicity Category II
- 0.51 mg/L and 1.5 mg/L in mice and rats, respectively

Primary dermal irritation: Toxicity Category IV
- No irritation observed in rabbit

Primary eye irritation: Toxicity Category III
Reversible mild irritation of conjunctivae in the rabbit

Acute delayed neurotoxicity: Data gap

Subchronic oral (rodent): Data insufficient to assess subchronic toxicity

Chronic feeding: Data gap

Oncogenicity: Data gap, rat and mouse

Metabolism: Data gap

Teratogenicity: Rat - Maternal NOEL = 1.5 mg/kg/day
Maternal LEL = 4.5 mg/kg/day
Developmental Toxicity NOEL = 1.5 mg/kg/day
Maternal ChE NOEL = 0.5 mg/kg/day (lowest dose tested)

Rabbit - Maternal NOEL = 0.2 mg/kg/day
Maternal ChE LEL = 0.8 mg/kg/day
Developmental Toxicity LEL = 0.05 mg/kg/day (lowest dose tested)
Maternal ChE NOEL = 0.2 mg/kg/day

Reproductive Effects: Rat - Reproductive NOEL = 1 ppm
Reproductive LEL = 10 ppm (decreased viability index and pup body weight, histopathological changes in epididymis)
Systemic NOEL = 1 ppm (decreased testes weight)

Mutagenicity: Data insufficient to assess mutagenic potential

Physiological and Biochemical Characteristics:

Metabolism and persistence in plants and animals

The metabolism of oxydemeton-methyl in plants is not adequately understood. Because of the structural similarity between disulfoton, demeton, and oxydemeton-methyl it is possible that certain metabolites of oxydemeton-methyl will be common to those of disulfoton and/or demeton. However, in the absence of adequate data delineating the nature of residues of oxydemeton-methyl in plants, no comparisons with demeton or disulfoton plant metabolism can be made at this time. Presently, oxydemeton-methyl and its cholinesterase-inhibiting metabolites are the residues of concern in plants. The tolerance definition may be revised to specifically include the metabolites which constitute residues of concern upon receipt of the requested data. The metabolism of oxydemeton-methyl in ruminants and poultry is not adequately understood. The only available in vivo ruminant metabolism study did not indicate what percentages of the total radioactivity in tissues and milk were present in the extracts of these samples. Additional metabolism studies in plants and animals are required.

Environmental Characteristics:

The environmental fate of oxydemeton-methyl cannot be fully assessed. With the exception of a hydrolysis study, available data reviewed by the Agency are not sufficient to fulfill the environmental fate data requirements. Available data are not adequate to fully assess leaching potential (e.g., field dissipation). Oxydemeton-methyl and its degradation products are soluble in water. Under aerobic conditions, as indicated by preliminary studies, oxydemeton-methyl breaks down in soils of different textures to dimethyl phosphate, 2-sulfonic diethyl sulfoxide, 2 sulfonic diethyl sulfone, and oxydemeton-methyl sulfone. The Agency cannot conclusively determine the potential for ground water contamination at this time.

Ecological Characteristics:

Avian Species

The avian acute oral studies with 50% ai oxydemeton-methyl indicate that the acute toxicity ranges from moderately toxic to highly toxic, depending on the species of bird tested. The acute toxicity values range from 14 mg/kg (rock dove) to 47.6 mg/kg (California quail) for the highly toxic range and from 53.9 mg/kg (mallard) to 120 mg/kg (Chuka) for the moderately toxic range. Likewise, 8-day dietary studies demonstrate that there is a wide range of toxicity from practically nontoxic (>5000 ppm for mallards) to highly toxic (434 ppm for bobwhite quail). Additional data are not required.

No acceptable avian reproduction studies are available. Data are required to support uses of oxydemeton-methyl on crops with multiple applications such as cotton, alfalfa, grapes and sugar beets.

Avian terrestrial field studies are not required. A comparison of the acute toxicity values with estimated pesticide residues on food items indicate that birds will not be exposed to lethal concentrations of oxydemeton-methyl in the field at application rates up to 0.75 lb ai/A (the highest rate currently registered).

Aquatic Organisms

The acute toxicity tests with freshwater invertebrates indicate that oxydemeton-methyl is very highly toxic to daphnids (3.3 ppb), moderately toxic to isopods (1400 ppb), and moderately to highly toxic to amphipods (190 to 1000 ppb). However, none of the available studies satisfies the requirement for an acute toxicity study for freshwater invertebrates since older specimens were used in the tests. A new study is required.

The acute fish studies indicate that oxydemeton-methyl is moderately to highly toxic to coldwater fish and slightly to moderately toxic to warmwater fish. The 96-hour acute toxicity values ranged from 0.73 ppm to 6.4 ppm for rainbow trout and from 1.22 ppm to 31.5 ppm for several species of warmwater fish. Additional data are not required.

Evaluation of tests on a 25% ai oxydemeton-methyl concentrate product, indicates this formulation is moderately toxic to estuarine crustaceans. The 96-hour acute toxicity value for pink shrimp (Penaeus duorarum) was 1.2 (0.9-1.8) ppm, and the 96-hour acute toxicity value for fiddler crab was 8.6 (6.6-11) ppm. Based on currently registered uses, oxydemeton-methyl is not expected to enter estuarine environments in significant concentrations. Additional acute toxicity testing on estuarine organisms is not required.

Nontarget Insects

Studies indicate that oxydemeton-methyl is moderately to highly toxic to honey bees exposed to direct application. However, toxicity of foliar residues appears to be short lived. Toxicity to honey bee larvae is highly variable depending upon larval development at the time of exposure. It is unlikely that these nontarget insects would be affected by application of oxydemeton-methyl made in accordance with label directions.

Tolerance Reassessment

Tolerances have been established for residues of oxydemeton-methyl expressed in terms of combined residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites on various raw agricultural commodities (40 CFR 180.330).

A feed additive tolerance of 2.0 ppm is established for the combined residues of oxydemeton-methyl and its cholinesterase inhibiting

metabolites in the milled fractions of sorghum (except flour) for animal feed when present therein as a result of application to growing sorghum (21 CFR 561.234).

Because of the extensive residue chemistry and toxicology data gaps, the Agency cannot complete all tolerance reassessments.

4. Required Labeling and Regulatory Position Summary

Oxydemeton-methyl is being placed into Special Review: The Agency is initiating a Special Review on all uses of pesticide products containing oxydemeton-methyl, based on concerns regarding reproductive effects. The Agency has determined that oxydemeton-methyl has the potential to induce reproductive effects in humans, and that that effect is of concern because of the potential exposures of applicators, mixers and loaders who use products containing oxydemeton-methyl, and to field workers entering treated fields.

The following precautionary measures are being required for all products containing oxydemeton-methyl either as a single active ingredient or in combination with other active ingredients, pending receipt and evaluation of additional data which will allow the Agency to fully assess the potential of oxydemeton-methyl to induce adverse effects.

Use Classification: All products containing oxydemeton-methyl are classified for Restricted Use under this Standard, on the basis of the potential for reproductive effects.

Protective Clothing/Equipment and Closed Systems: The use of maximum full body protective clothing/equipment by mixer/loaders/applicators, and by field workers entering treated fields prior to the end of the 48 hour reentry interval is required.

Reentry Interval: The 48-hour reentry interval established under 40 CFR 170 for all agricultural uses of oxydemeton-methyl which may involve hand labor tasks will continue to be required. In addition, the use of maximum protective clothing and equipment is required if treated fields are entered prior to the end of the reentry interval. Reentry data are being required to reassess the adequacy of the 48 hour reentry interval.

Flaggers: The use of human flaggers during aerial application is prohibited, unless they are in totally enclosed vehicles.

Tolerances: No new tolerances and food uses will be granted until the Agency has received data sufficient to evaluate the dietary exposure to oxydemeton-methyl.

5. Summary of Major Data Gaps

Toxicology:	Date Due *
Acute Oral	9 Months
Dermal Sensitization (Guinea pig)	9 Months
Acute Delayed Neurotoxicity (Hens)	12 Months
Subchronic Oral - Rat	15 Months
- Non-rodent	18 Months
(Not required if chronic data are acceptable)	
Subchronic Dermal (21-Day; Rabbit)	12 Months
Subchronic Neurotoxicity	15 Months
(Required if acute delayed neurotoxicity is positive)	
Chronic Toxicity (Rat, dog)	50 Months -
Oncogenicity (Rat, Mouse)	50 Months
Mutagenicity Tests (Chromosomal and DNA)	12 Months
Metabolism (General)	24 Months
Male Short Term Exposure Study	10/31/88
Male Reproductive System Toxicity Study	12/31/87**

Environmental Fate/Exposure	
Photodegradation	
In water	9 Months
In soil	4 Months
In air (condiditonal)	
Metabolism - Lab	
Aerobic Soil	27 Months
Anaerobic Soil	7/14/88
Mobility	
Leaching and Adsorption/Desorption	12 Months
Laboratory Volatility	12 Months
Field Volatility (conditional)	
Terrestrial Field Dissipation	
Field Dissipation - Soil	27 Months
Long-term Field Dissipation (conditional)	
Confined Rotational Crop	07/14/89
Field Rotational Crop (conditional)	
Spray Drift Studies	
Droplet Size Spectrum	27 Months
Drift Field Evaluation	27 Months
Reentry	
Foliar Dissipation	27 Months
Soil Dissipation	27 Months
Dermal Exposure (conditional)	
Inhalation Exposure (conditional)	

* Due date is based on date of receipt of Standard by the registrant, unless otherwise indicated.

** Study required by the June, 1987 Data Call-in and is to be submitted by either December 31, 1987 (if an ongoing study being conducted by Mobay for the California Dept. of Food and Agric. is used) or October 31, 1988 (if a new study is undertaken).

Ecological Effects	Date Due*
Avian Reproduction	04/14/88
Aquatic Invertebrate Acute Toxicity	9 Months
Fish Early Life Stage and Aquatic Invertebrate Life Cycle	15 Months
Aquatic Organism Accumulation	27 Months

Residue Chemistry/Product Chemistry	
Product Chemistry	6 - 12 Months
Plant and Animal Metabolism	10/14/87 -
Storage Stability	24 Months
Magnitude of Residue Studies	4/14/88

6. Contact Person at EPA

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